EFFECT OF ADJUVANT YOGA THERAPY ON NONULCER DYSPEPSIA AMONG PATIENTS IN A TERTIARY CARE HOSPITAL: A RANDOMISED CONTROLLED TRIAL

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1. Introduction

1.1 Definition

Functional Dyspepsia (FD) or non-ulcer dyspepsia is a Disorder of Gut-Brain Interaction (DGBI) involving the upper gastrointestinal tract [1]. DGBIs, previously known as Functional Gastrointestinal Disorders (FGIDs) result from disordered communication between the gut and brain. Symptoms of FD include pain or discomfort in upper abdomen, epigastric burning, fullness after meals, early satiety or unable to finish meals. There may be associated symptoms like bloating, nausea, belching etc. Diagnosis of FD includes absence of any structural or organic disease found during upper endoscopy and fulfilment of Rome -IV criteria [2].

Rome-IV categorizes FD into broadly two categories: (i) Epigastric Pain Syndrome (EPS) which includes presence of bothersome epigastric pain or/and burning, at least once a week for 3 months with symptom onset at least 6 months prior. (ii) Postprandial Distress Syndrome (PDS) which includes bothersome fullness after meals or/and early satiety present at least 2-3 days a week for 3 months with symptom onset at least 6 months prior [3].

1.2 Epidemiology

The estimated prevalence of FD in the Rome Foundation global survey, as per Rome IV criteria in the general population stands at 7.2% [4]. In India prevalence of uninvestigated dyspepsia (UD) is estimated between 7.5% and 49% differing across various states [5].

1.3 Risk Factors

Studies suggest that female gender, smoking, non-steroidal anti-inflammatory drugs (NSAIDs), acute gastrointestinal infections, childhood abuse, psychological distress (including perceived stress, anxiety and depression), and Helicobacter Pylori (H. pylori) bacteria are some risk factors for developing FD [6]. In Asia, heavy chili intake is implicated too.

1.4 Pathophysiology

The pathophysiology of FD is complex and incompletely understood. It is attributed to disordered communication between the gut and the brain which may cause abnormal gastrointestinal functioning like motility disturbances, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota and central nervous system (CNS) processing. An infection or allergen (leading to low-grade duodenal inflammation), increased acid exposure, psychological distress coupled with a weak vagal tone may trigger this abnormal gut-brain interaction.

1.5 Treatment

Standard Medical Management (SMM) recommends H. pylori eradication therapy in case of H. pylori-positive patients failing which proton-pump inhibitor (PPI) therapy is advised. In case of H. pylori-negative individuals, PPI is recommended as a first-line therapy, failing which Tricyclic Antidepressant (TCA) is recommended by American College of Gastroenterology/Canadian Association of Gastroenterology (ACG/CAG) combined guidelines as a second-line therapy for FD. Prokinetic is recommended if the above therapy fails [7].

1.6 Yoga

Yoga is an ancient Indian mind-body practise which aim to control the fluctuations of mind. The word yoga is a Sanskrit term which is derived from the root word “yuj” meaning to unite the mind, body and soul. It comprises of physical, mental and spiritual practices for achieving complete state of health and wellness. Yoga therapy is defined by International Association of Yoga Therapists (IAYT) as, “the process of empowering individuals to progress toward improved health and well-being through the application of the teachings and practices of Yoga”. Yoga practices work both on mind and body, hence working on a variety of psychological as well as physiological disorders. It is hypothesised to work by balancing the autonomic nervous system and enhancing the parasympathetic tone and decreasing the sympathetic tone. Yoga may have more direct physiological effects, affecting the peripheral systems directly.

1.7 Need of Study

FD is a chronic disorder which impacts the Quality of Life (QoL) of patients, causes psychological distress and incurs significant healthcare cost. The efficacy of the standard medical management in FD remains modest and treatment remains unsatisfactory for many patients [8]. Their long term use is further associated with side-effects like, PPI usage may cause diarrhoea, small intestinal bacterial overgrowth (SIBO), impaired digestion. Some prokinetics drugs may prolong QT interval. Hence, there is a need to investigate additional interventions which adopt a biopsychosocial approach and can address the gut-brain axis bidirectionally. Complementary and Alternative Medicine (CAM) therapies like acupuncture, hypnotherapy, herbal medicines have been in use for FD with studies showing beneficial effect but limited to certain ethnic populations. Role of Yoga therapy in other DGBIs like Irritable Bowel Syndrome (IBS) has been studied and has proven significant benefit but apart from one study on Functional Abdominal Pain Disorders that include few FD patients as well, no other study deals with Yoga and FD as per our best knowledge. Yoga therapy has a holistic approach and can be easily integrated with the medical treatment. It can play a bi-directional role in modulating the gut-brain axis. While role of yoga in reducing stress, anxiety and depression is well established, we find references from traditional yogic text where certain yoga practices like *dhauti* (one of the six cleansing practice), *asanas* (postures) and *pranayama* (breathing practices) help in cleansing the gut and restoring digestion. It may work by reducing inflammation in the gut, restoring mucosal and epithelial barrier and restoring the gut microbiota. Very few studies have been conducted on these physiological benefits and needs more studies to confirm its action. Yoga also increases awareness of body and mind which can empower the individual to aid his/her healing.

2. Aims & Objectives

2.1 Aim:

To study the effect of adjuvant yoga therapy (AYT) on functional (nonulcer) dyspepsia among patients in a tertiary care hospital.

2.2 Objectives:

i. To evaluate the effect of Yogic practices on major symptoms of dyspepsia including epigastric pain, burning, bloating, belching, nausea and vomiting.
ii. To assess the change in Dyspepsia specific quality of life using Nepean Dyspepsia Index.
iii. To evaluate the effects of Yogic practices on psychological parameters like stress, anxiety and depression in dyspepsia patients.

3. Research Question

Is adjuvant Yoga therapy with standard medical management more effective than standard medical management alone in the treatment of functional (non-ulcer) dyspepsia?

4. Brief Review of Literature

4.1 Standard Medical Management for FD

Given evidence of impaired duodenal clearance of gastric acid and duodenal hypersensitivity to infused gastric acid, acid suppression is a logical treatment in FD. However, studies have shown modest benefit of PPIs over placebo. In a Cochrane review conducted by **Pinto-Sanchez et al (2017) [9]**, PPI therapy was slightly more effective than placebo, with 30% of the PPI group reporting no or minimal symptoms compared with 25% of the placebo group (Risk Ratio or RR of remaining dyspeptic 0.88, 95% CI 0.82 to 0.94; $P < 0.001$) with a number needed to treat (NNT) of 13. In another systematic review by **Wang et al (2007) [10]**, PPIs (40.3%) were more effective compared with placebo (32.7%), yielding a Relative Risk Ratio or RRR of 10.3% (95% CI, 2.7%–17.3%, $P < 0.005$). The estimated NNT was 14.6 patients (95% CI, 8.7–57.1 patients).

Sanaka et al (2010) [11] in their review suggested that PPIs delayed the gastric emptying of solid meals as they impair hydrolytic digestion by inhibiting acid-dependent peptic activity. Nonetheless, recent studies have also pointed out to their beneficial role in PDS.

Prokinetics help postprandial distress more than epigastric pain or burning. But they must be used with caution as few of these drugs prolong QT interval. TCAs such as amitriptyline and imipramine are found to be effective but not selective serotonin reuptake inhibitors. Also, the level of evidence for neuromodulators in Asian population is weak .

4.2 Complementary & Alternative Medicine (CAM) therapies for FD

Given the limited efficacy of the aforementioned pharmacologic therapies, approximately 50% of patients with gastrointestinal symptoms are estimated to try CAM therapies for symptom relief. CAM therapies that have been used in FD include herbal medicines, acupuncture, and hypnotherapy with varying degrees of efficacy [12]. In spite of being one of the most prevalent DGBI, not much has been studied on the use of Yoga therapy for the management of FD, though its use in other DGBIs like IBS, and Functional Abdominal Pain Disorders (FAPDs) has been studied.

4.3 Yoga for DGBIs

Yoga therapy has shown beneficial effects in DGBIs like IBS and FAPDs.

4.3.1 Yoga for FAPDs

Disorders under FAPDs include IBS, FD, Abdominal Migraine, and Functional Abdominal Pain-Not Otherwise Specified (FAP-NOS). Majority of studies have focussed only on patients with irritable bowel syndrome. Yoga therapy for IBS has been discussed in 4.3.2. Other studies with FADPs have focussed mainly on FAP and IBS with their inclusion criteria mentioning only these two disorders. In the most recent study by **Högström et al**., in girls between the ages of 9 and 13 with IBS or FAP (Rome III criteria), yoga and dance combination therapy significantly lowered maximum abdominal pain scores more than the Standard Medical Care (SMC) group at 4 and 8 month follow-up ($p < .003$ and $p < .002$ respectively) [13]. Though FAP is not strictly FD, the efficacy and safety of these options suggest that it is a likely beneficial treatment modality for DGBIs, including FD.

Only one study done on FAPDs by Korterink et al et al in paediatric population have included FD as well which is discussed in point 4.3.3

4.3.2 Yoga for IBS

In a systematic review done by **Schumann et al (2016)** involving six RCTs, Yoga therapy was found to be beneficial over conventional treatment, with significantly decreased bowel symptoms, IBS severity, anxiety and QoL [14].

In an RCT done by **Taneja et al (2004)** on diarrhoea-predominant irritable bowel syndrome [15] comparing the effectiveness of an unsupervised Yoga intervention twice a day for 2 months to loperamide 2–6 mg/ day for 2 months, improvement was noted in IBS symptom severity and gastric motility in both groups without significant difference between groups. Autonomic symptom scores showed a marginally significant difference with better improvement in Yogic group.

4.3.3 Yoga for FD

Studies directly involving Yoga therapy with FD patients have not been done as per our best knowledge. Only one RCT by ***Korterink et al (2016)*** involving 69 children with abdominal pain related DGBIs (AP-DGBIs) now called as FADPs, yoga therapy in addition to standard medical management (SMM) showed higher treatment response of 58% as compared to 29% in SMM only group [16]. The FADPs in this study included **IBS (37.7%), FAPs (50.7%)** and **FD (11.6%)**. Yoga therapy was more effective in reducing pain intensity, monthly school absence but was not significantly more effective in improving pain frequency or QoL. However, there was no separate analysis with regard to improvement in pain in FD subjects. Also, it was a research focused on pain symptoms solely and other symptoms of FD were not the subject matter of the study.

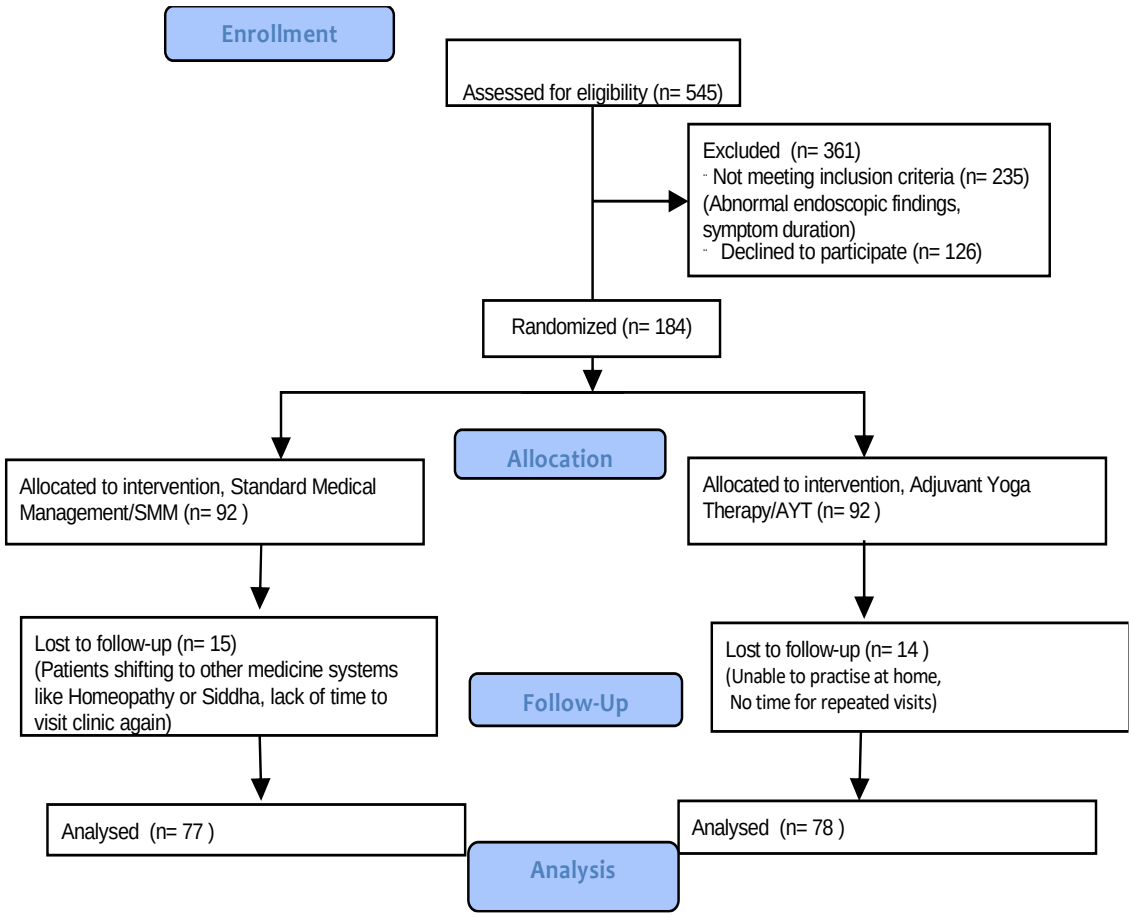
Apart from this a study was done by **Ismail et al** on perimenopausal women with FD [17]. The intervention did not involve Yoga therapy but had two groups, one involving Benson's relaxation therapy (BRT) alone and other study group involving aerobic exercise plus BRT. Both groups reported significant improvements in all measured variables including Glasgow Dyspepsia Severity Score (GDSS), cortisol levels, Pittsburgh sleep quality index (PSQI), and depression, anxiety, and stress scales (DASS-42) except for estradiol that was significant only in study group. BRT with aerobic exercise was significant over BRT alone in GDSS, PSQI, DASS 42 but not in cortisol or estradiol.

In a survey study done by **Koloski et al** patients with FD (ROME-III criteria) reported significantly less walking (57% vs 63%, p=0.04) and lower frequency of exercising, including walking (p=0.008), moderate (p= 0.03) and vigorous activity (p=0.02), compared with controls [18].

5. Methodology

5.1 CONSORT

The enrollment of the participants in the study is summarised in the CONSORT diagram (Figure 1). It illustrates the flow of the participants through the study, including the number of participants screened, excluded, randomized, and analysed. This figure provides a clear and concise overview of the study design and participant flow and serves as a helpful reference for interpreting the main findings of the trial.


Enrollment
Assessed for eligibility (n= 545)
Excluded (n= 361)
Not meeting inclusion criteria (n= 235) (Abnormal endoscopic findings, symptom duration)
Declined to participate (n= 126)
Randomized (n= 184)
Allocation
Allocated to intervention, Standard Medical Management/SMM (n= 92)
Allocated to intervention, Adjuvant Yoga Therapy/AYT (n= 92)
Lost to follow-up (n= 15) (Patients shifting to other medicine systems like Homeopathy or Siddha, lack of time to visit clinic again)
Follow-Up
Lost to follow-up (n= 14) (Unable to practise at home, No time for repeated visits)
Analysed (n= 77)
Analysis
Analysed (n= 78)

5.2 Study Design

This study is a parallel-group, single-center, open-label randomised controlled trial. Prior permission was taken for the study from the Institutional Human Ethics Committee (IHEC) [Project No: Ph.D. Project/04/2019/004]. and registered with the Clinical Trials Registry of India, CTRI/2019/10/ 021,773 [Registered on: 23/10/2019].

5.3 Place of Study

The study was conducted at the School of Yoga Therapy (SYT), Institute of Salutogenesis and Complementary Medicine (ISCM) & Mahatma Gandhi Medical College & Research Institute (MGMC&RI), Sri Balaji Vidyapeeth (SBV) Deemed-to-be University, Puducherry.

5.4 Patient selection

5.4.1 Study Population

Patients having symptoms of dyspepsia undergoing endoscopy.

5.4.2 Inclusion Criteria

1. Patients diagnosed with FD after undergoing endoscopy & fulfilling Rome-IV criteria.
2. No evidence of any structural or organic disease in endoscopy.
3. Age limit of 18 - 65 years.
4. Able to perform techniques in the protocol.
5. Willingness to participate in Yoga Therapy.

5.4.3 Exclusion Criteria

Peptic Ulcer Disease (PUD), gastroesophageal reflux disease (GERD), gastric carcinomas, hematemesis, hiatal hernia, congenital malformations, liver disease, history of recent surgery within 6 months, heart disease, hypertension, epilepsy, bleeding piles.

5.4.4 Study Subjects

Our study involves patients with a clinical diagnosis of FD who had undergone endoscopy and fulfilled inclusion & exclusion criteria.

5.4.5 Sample Size

Sample size arrived at using sample size calculator for 2 proportion is 77 for each group,

Therefore minimum required sample size would be 154. Adding a dropout rate at 20%, 184 sample size is required to fulfil the minimum required sample size.

$$n \geq \frac{\left[Z_{1-\alpha/2}\sqrt{(r+1)p(1-p)} + Z_{1-\beta}\sqrt{rp_1(1-p_1)+p_2(1-p_2)}\right]^2}{r(p_2-p_1)^2}$$

$Z_{1-\alpha/2}$ = 1.96 at 95% of confidence with $\alpha = 0.05$

$Z_{1-\beta}$ = 0.84 at 80% of power with $\beta = 0.20$

p_1 = 66.9 % from previous study

p_2 = 86% expected to get symptom relief

$p = (p_1 + rp_2) / (1+r)$

n = 77 in each group

The total sample size is 154

5.4.6 Sampling Procedure

Purposive Sampling was used for the study

5.5 Patient Allocation/Randomisation

Patients (n=155) were block randomised into two groups, Standard Medical Management (SMM) group & Adjuvant Yoga Therapy (AYT) group using random allocation software generated list with a block size of 4 and in a 1:1 ratio. SMM group received the standard medical care while AYT group received Yoga therapy along with standard medical care for a period of three months.

5.6 Outcome Measures/ Tools Used

Rome-IV Diagnostic Questionnaire and Short Form - Nepean Dyspepsia Index (SF-NDI) were used to assess the symptoms of functional dyspepsia and disease-specific QoL. Perceived Stress scale (PSS), Generalised Anxiety Disorder – 7 (GAD-7) and

Patient Health Questionnaire – 9 (PHQ-9) were used to assess stress, anxiety and depression respectively.

5.6.1 Rome-IV Diagnostic Questionnaire for Adults (Gastroduodenal Module)

The Rome-IV gastroduodenal module consists of questions for various disorders of gastroduodenal origin. Out of these, questions 14-20 (7 questions) deals with functional dyspepsia. Q 14-17 are concerned with PDS and comprises of the following criteria, bothersome postprandial fullness (i.e., severe enough to impact on usual activities) at least 2-3 days per week and/or bothersome early satiation (i.e., severe enough to prevent finishing a regular size meal) at least 2-3 days per week. Q. 18 -20 deals with the criteria for EPS, which is, bothersome epigastric pain (i.e., severe enough to impact on usual activities) and/or bothersome epigastric burning (i.e., severe enough to impact on usual activities) with symptom onset at least 6 months prior to diagnosis. Also, scoring algorithm clearly states that there should be no evidence of organic, systemic, or metabolic disease that is likely to explain the symptoms on routine investigations (including at upper endoscopy).

5.6.2 Short Form - Nepean Dyspepsia Index (SF-NDI)

SF-NDI consists of two sections. The first section deals with fifteen symptoms of FD. Each symptom is further divided into the frequency, intensity, and bothersomeness that a person has had in the last two weeks. Second section deals with dyspepsia-specific QoL which is further subdivided into five domains, viz, tension, interference, eating/drinking, knowledge/control, and work. Each subdomain consists of two questions.

Scoring: Frequency is scored as: 0 = Not at all, 1 = One to four days, 2 = Five to eight days, 3 = Nine to twelve days, 4 = Every day / almost every day; Intensity is scored as: 0 = Not at all, 1 = Very mild, 2 = Mild, 3 = Moderate, 4 = Severe, 5 = Very severe; Bothersome - 0 = Not at all, 1 = A little bit, 2 = Moderately, 3 = Quite a bit, 4 = Extremely. The total of all these three gives the symptom score of that particular symptom, and the total of all 15 symptoms give total symptom score (Range 0- 195). For the scoring of QoL, each subsection range of scores can be 2-10. For calculating

each subdomain score, the formula is as follows: 100-(subscale score - 2)/10*100. To calculate total QoL, all five subdomain scores are added and then divided by 5.

5.6.3 The Perceived Stress Scale (PSS)

PSS developed by Sheldon Cohen, is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. The PSS was designed for use in community samples with at least a junior high school education. The items are easy to understand, and the response alternatives are simple to grasp.

Scoring: The scoring is done as: "0" for "never", "1" for "almost never", "2" for "sometimes", "3" for fairly often, "4" for "very often". For the four positively stated items (items 4, 5, 7, & 8), PSS scores are obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) and then summing across all scale items.

5.6.4 Generalized Anxiety Disorder (GAD-7)

GAD-7 is a 7-item module from the full PHQ questionnaire for measuring generalised anxiety disorder. Though originally developed to diagnose generalized anxiety disorder, the GAD-7 also proved to have good sensitivity and specificity as a screener for panic, social anxiety, and post-traumatic stress disorder.

Scoring: Each of the seven items are scored from 0 to 3, "0" for "not at all", "1" for "several days", "2" for "more than half the days", "3" for "nearly every day", providing a 0 to 21 severity score.

5.6.5 Patient Health Questionnaire (PHQ-9)

The PHQ – 9 is the 9-item depression module from the full PHQ (Patient Health Questionnaire) which assess 8 diagnosis. It is a self-administered version of the PRIME-MD diagnostic instrument for common mental disorders.

Scoring: The PHQ-9 scores each of the 9 DSM- IV criteria as "0" (not at all) to "3" (nearly every day). Each of the 9 item is scored from 0 to 3, providing a 0 to 27 severity score. At 9 items, the PHQ depression scale (called PHQ – 9) is half the length of many

other depression measures, has comparable sensitivity and specificity and consists of the actual 9 criteria upon which the diagnosis of DSM- IV depressive disorder is based.

5.7 Yoga Therapy Protocol

Based on traditional references [19] and previous research studies [20] the following practices were shortlisted after expert validation (Table 1).

Table 1: Yoga therapy protocol

S.No.	Yogic Techniques	Rounds	Minutes
1.	Deep breathing	5-10	5 mins
2.	Vatasara Kriya	5-10	5 mins
3.	Varisara Kriya (Laghoo Shankh Prakshalana)	One cycle consists of 3 rounds (Once/ twice a week)	30 mins
4.	Kapalbhati	2 rounds	3 mins
5.	Sukshma Vyayama	One full cycle	10 mins
6.	Suryanamaskar	2-4 rounds	5 mins
7.	Shavasana	One full cycle	5 mins
8.	Nadishuddhi	5- 10 rounds	10 mins
9.	Sheetali	5 rounds	2 mins
10.	Sitkari	5 rounds	2 mins
11.	A-U-M Chanting	3 rounds	1 min

These practices were taught gradually in a step-by-step manner adding components weekly illustrated in Table 2.

Table 2: Weekly Yoga practise schedule

S.No.	Practices	Duration/Repetitions			
		Week 1	Week 2	Week 3	Week 4
1	Yogic Deep Breathing (i) Chest breathing (ii) Abdominal Breathing	5 rounds 5 rounds 5 rounds	5 rounds - -	5 rounds - -	5 rounds - -
2	Nadi Shuddhi	5 rounds	5 rounds	10 rounds	10 rounds
3	Vatasara Vatasara with holding	5-10 rounds -	10 rounds -	5 rounds 5 rounds	5 rounds 5 rounds
4	Laghoo Shankh Prakshalana	-	-	Twice a week	Once a week
5	Kapalabhati	-	-	2 rounds (20-30 strokes each) Twice a week	2 rounds (20-30 strokes each) Twice a week
6	Sukshma Vyayama	Neck & Shoulders	Neck, Shoulders & arms Waist & Legs	Neck, Shoulders & arms Waist & Legs	Neck, Shoulders & arms Waist & Legs
7	Suryanamaskar	-	-	2 rounds	2-4 rounds
8	Shitali	5 rounds	5 rounds	5 rounds	5 rounds
9	Shitkari	5 rounds	5 rounds	5 rounds	5 rounds
10	Shavasana	5 mins	5 mins	5 mins	5 mins
11	Om Chanting	3 times	3 times	3 times	3 times

5.8 Procedure/Conduct of the Study

1) The patients with symptoms of dyspepsia undergoing endoscopy were screened by the gastroenterologist.
2) Those who were diagnosed as FD and found eligible for the study were referred to Yoga therapy.

3) After fulfilling inclusion and exclusion criteria, subjects were randomized into experimental (Adjuvant Yoga Therapy) and control (Standard Medical Management) group through block randomization.
4) The subjects were informed about the study and their consent was taken.
5) Pre-data was collected with the help of questionnaires filled by patients at the start of the study.
6) While the subjects in SMM group received standard medical care, subjects in the AYT group received 3 supervised sessions at the beginning and another 3 sessions at a gap of 1 week for teaching cleansing practices.
7) Yoga videos were given to subjects in the AYT group for home practice.
8) Online sessions were conducted once a week via Zoom.
9) A step-by-step, graded approach was adopted and components of the yoga therapy protocol were added to the practice sessions every week based on the progress of the participant.
10) Minimum thrice a week practice at home and 10 Zoom sessions were considered as the cut-off for successful completion of the intervention.
11) Both SMM group and AYT group subjects were followed up regularly once a week for recording their compliance with medicines and yoga.
12) After 3 months, post-data was collected.
13) Treatment outcome was evaluated by noting how many subjects had ≥50 % relief in symptoms.
14) Patients who reported ≥ 50% relief were considered the responders group or high recovery group. And less than ≤50% relief was considered low recovery group or non-responders.

5.9 Statistical Analysis

- Median and Interquartile Range (IQR) values are used to represent numerical parameters which are not normally distributed.
- Chi-square (χ^2) was used to compare categorical variables between groups.
- Wilcoxon test is used for within the group and Mann-Whitney U test for between the group comparisons as the data was not normally distributed.
- Delta percentage (Δ %) was calculated by the formula (post-pre/pre) X 100 for all the outcome variables to evaluate the pre-post change in the scores.

- Treatment response was compared among the H. pylori-positive, H. pylori-negative and Unknown status (in which H. pylori testing was not done) group using KW-ANOVA with the Δ % values.
- Odds ratio was used to evaluate the clinical significance of symptomatic improvement.
- Fisher's exact test/chi-square test was used to evaluate clinical significance in psychological parameters.
- KW-ANOVA and post hoc Dunn's tests have been used for subgroup analysis.
- JASP (version 16.4) was used for all statistical analyses.

6 Result & Discussion

6.1 Socio-demographic data

The socio-demographic characteristics of the subjects which were collected include age, gender, marital status, education, occupation, socio-economic status and dietary habits. These data are considered intervening variables and therefore provide important context for interpreting the findings of the study, as they may interact with the interpretation of intervention outcomes. It also ensures if randomisation was successful. All socio-demographic variables were comparable at the baseline as determined by respective chi-square (χ^2) values.

6.2 Baseline Clinical variables

Clinical variables that were collected at the baseline include classification of symptoms as per Rome-IV guidelines in EPS, PDS and overlap categories, H. Pylori status, symptom profile and duration of the symptoms. The baseline clinical variables were comparable at the baseline as determined by respective chi-square (χ^2) values.

6.3 Effect of AYT on Dyspepsia Symptoms (using Nepean Dyspepsia Index)

Effect of SMM and AYT on fifteen (15) symptoms of dyspepsia individually and total symptom score using Nepean Dyspepsia Index is given in Table 3. The table provides a clear representation of the change in each symptom score in both the groups,

demonstrating the effect of SMM and AYT on each symptom score as well as total symptom score and also the comparison between both the groups.

Table 3: Effect of SMM and AYT on symptom score

S.No.	Symptom	SMM		AYT		p-value	
		B	A	B	A	B-B	A-A
1.	Pain or ache in upper abdomen	9 (0,12)	3 (0,5) ###	9 (0,11)	1.5 (0,4) ###	0.523	0.366
2.	Discomfort in upper abdomen	0 (0,6)	0 (0,3) ###	0 (0,8)	0 (0,3) ###	0.152	0.678
3.	Epigastric burning	10 (5,12)	3 (0,5) ###	9.5 (0,12)	1.5 (0,3) ###	0.694	0.11
4.	Heartburn	0 (0,6)	0 (0,3) ###	0 (0, 6.75)	0 (0, 2.25) ###	0.928	0.842
5.	Cramps	0 (0,4)	0 (0,0) ###	0 (0,3)	0 (0,0) ###	0.554	0.593
6.	Chest pain	0 (0,0)	0 (0,0) ###	0 (0,0)	0 (0,0) ##	0.557	0.163
7.	Early satiety	6 (0,9)	3 (0,4) ###	5 (0,8)	0 (0,3) ###	0.464	**0.009****
8.	Regurgitation	0 (0,6)	0 (0,0) ###	0 (0,5.75)	0 (0,0) ###	0.631	0.683
9.	Postprandial fullness	9 (0,12)	4 (0,6) ###	10 (0,11)	3 (0,3) ###	0.793	**<0.001*****
10.	Pressure in upper abdomen	0 (0,0)	0 (0,0) ##	0 (0,0)	0 (0,0) ###	0.846	0.256
11.	Bloating	7 (0,10)	3 (0,6) ###	7 (3,10)	3 (0,3) ###	0.493	**0.003****
12.	Nausea	3 (0,8)	0 (0,3) ###	3 (0,6)	0 (0,0) ###	0.361	**0.006****
13.	Burping/belching	0 (0,8)	0 (0,3) ###	0 (0,7)	0 (0,0) ###	0.34	**0.03***
14.	Vomiting	0 (0,0)	0 (0,0) ###	0 (0,0)	0 (0,0) ##	0.312	0.236
15.	Bad breath	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0.749	0.475
Total Symptom Score		52 (44,64)	22 (15,31) ###	52 (42,63.75)	15 (7.25, 21) ###	0.749	**<0.001*****

Values are given as Median (IQR) for 77 subjects in SMM group and 78 subjects in AYT group. Wilcoxon test is used for intra-group comparisons where # p<0.05, ##p<0.01, ###p< 0.001; *Mann- Whitney U test is used for inter-group comparisons. *p<0.05, **p<0.01, ***p< 0.001. Actual p values are given for inter-group comparisons.

- Between the group comparison, AYT is significant over SMM in reducing total symptom score (p<0.001).
- While AYT has no additional benefit over SMM in improving epigastric pain, burning, regurgitation and vomiting, it has significantly more benefit in alleviating postprandial fullness, early satiety, bloating, burping and nausea.

Delta percentage (Δ %) was calculated by the formula (post-pre/pre) X 100 for total symptom score (TSS). In SMM group, there is a decrease of 56.14% (IQR - 47.27,72.73) in TSS, while in AYT Δ % is 73.2% (IQR - 65.29,83.72). The difference in the Δ % value between the two groups is significant at $p<0.001$.

Also, patients who reported ≥ 50% relief were considered responders group or high recovery group. And less than ≤50% relief was considered low recovery group or non-responders. Odds ratio was calculated using proportion of patients in responder vs non-responder group.

It was found in our study that in AYT groups there is almost 6 times (OR 6.611, CI – 2.37 – 18.45) more chances of high recovery than SMM group.

6.4 Effect of AYT on Dyspepsia specific QoL

Table 4 illustrates and compares the effect of SMM and AYT on five subdomains of QoL as well as the total QoL score in dyspepsia patients using the Nepean Dyspepsia QoL index. The table provides a clear representation of the improvement in QoL score in both groups as well as the comparison between both groups.

Table 4: Effect of SMM and AYT on dyspepsia-specific QoL

S.No	QoL subdomains	SMM		AYT		P value	
		B	A	B	A	B-B	A-A
1.	Tension	50 (40,60)	80 (60,90) ###	60 (40,67.5)	90 (90,100) ###	0.968	<0.001 ***
2.	Interference	60 (50,80)	90 (80,100) ###	60 (40,70)	100 (90,100) ###	0.199	<0.001 ***
3.	Eating/Drinking	40 (40,60)	80 (60,90) ###	50 (40,60)	90 (90,100) ###	0.264	<0.001 ***
4.	Knowledge/Control	80 (70,90)	90 (90,100) ###	80 (70,90)	100 (100,100) ###	0.787	<0.001 ***
5.	Work	60 (40,70)	90 (80,100) ###	60 (40,67.5)	100 (90,100) ###	0.457	<0.001 ***
Total QoL		60 (50,68)	86 (74,92) ###	60 (48.5,70)	96 (88,98) ###	0.618	<0.001 ***

Values are given as Median (IQR) for 77 subjects in SMM group and 78 subjects in AYT group. #Wilcoxon test is used for intra-group comparisons where # p<0.05, ##p<0.01, ###p< 0.001; *Mann- Whitney U test is used for inter-group comparisons. *p<0.05, **p<0.01, ***p< 0.001. Actual p values are given for inter-group comparisons.

- While both groups have significant improvement in QoL, between groups comparison show AYT significant over SMM in improving QoL ($p<0.001$).

Delta percentage (Δ %) was calculated for QoL. In SMM group, there is an increase of 35.48 % (IQR - 25.64, 52.38) in QoL, while in AYT the increase in QoL is 56.46 % (IQR - 37.14, 81.3). The difference in the Δ % value between the two groups is significant at $p<0.001$.

6.5 Effect of AYT on psychological parameters

Effect of SMM and AYT on various psychological parameters including stress, anxiety and depression is given in Table 5. The table provides a clear representation of the reduction in stress, anxiety as well as depression scores in both the groups as well as comparison between the groups.

Table 5: Effect of SMM and AYT on psychological parameters

Psychological Parameters	SMM		AYT		p-value	
	B	A	B	A	B-B	A-A
PSS	21 (19,23)	19 (18,21) ###	21 (19,23)	18 (17,19) ###	0.780	0.001***
GAD-7	8 (6,11)	6 (5,8) ###	8.5 (7,11.75)	4 (4,5) ###	0.226	<0.001***
PHQ-9	8 (5,10)	5 (4,7) ###	8 (6,10)	4 (3,5.75) ###	0.385	<0.001***

Values are given as Median (IQR) for 77 subjects in SMM group and 78 subjects in AYT group. #Wilcoxon test is used for intra-group comparisons where # $p<0.05$, ##$p<0.01$, ###$p< 0.001$; *Mann- Whitney U test is used for inter-group comparisons. *$p<0.05$, **$p<0.01$, ***$p< 0.001$. Actual p values are given for inter-group comparisons.

- **<u>AYT is significant over SMM in improving perceived stress score, anxiety and depression ($p<0.001$).</u>**

Delta percentage (Δ %) was calculated for PSS, GAD-7 and PHQ-9 scores.

- In SMM group, there is a decrease of 1% (IQR – 0,2) in PSS, while in AYT the decrease in PSS is 3% (IQR – 2,4). The difference in the Δ % value between the two groups is significant at $p<0.001$.
- Similarly in GAD-7 scores, there is a decrease of 25% (IQR – 16.67, 33.33) in SMM group while there is a decrease of 50% (IQR - 42.86,57.14) in AYT group. The difference in the Δ % value between the two groups is significant at $p<0.001$.
- In PHQ-9 scores, there is a decrease of 25% (IQR – 16.67, 33.33) in SMM group while there is a decrease of 40.83 (IQR - 33.33, 51.79). The difference in the Δ % value between the two groups is significant at $p<0.001$.

The results though show statistical significance; however, it is imperative to analyse clinical significance by evaluating whether subjects moved from high or severe psychological distress to low or minimal distress. Fisher's exact test/chi-square test was used to determine whether the results were clinically significant. The scores were categorised into their respective categories as per the scoring algorithm of PSS, GAD-7 and PHQ-9.

- In AYT group, while 6 people showed improvement in PSS scores out of 78 people, none of the subjects improved in SMM group. Here improvement signifies transformation or shifting from a higher stress category to lower. Fisher's exact test shows significant difference between the groups ($p=0.028$).
- Similarly, 71 out of 78 subjects in AYT group showed improvement in GAD-7 scores, while only 31 subjects out of 77 improved in SMM group. Chi-square test shows significant difference between the groups ($p<0.001$).
- While 57 subjects showed improvement in PHQ-9 scores in AYT group, only 32 subjects improved in SMM group. Chi-square test shows significant difference between the groups ($p<0.001$).

6.6 Effect of AYT in various subgroups of FD as per Rome-IV

Using the Rome-IV questionnaire, subjects were further divided into three subgroups of FD, viz, EPS, PDS and overlap groups. The subgroup analysis thus obtained is illustrated in Figure 1-5. Figure 1 represents the effect of both SMM and AYT on change in TSS in all three subgroups of FD. Figure 2 represents the effect of both SMM

and AYT on improvement in QoL in all three subgroups of FD. Figure 3 represents the effect of both SMM and AYT on change in PSS scores in all three subgroups of FD. Figure 4 represents the effect of both SMM and AYT on change in GAD-7 scores in all three subgroups of FD. Figure 5 represents the effect of both SMM and AYT on change in PHQ-9 scores in all three subgroups of FD.

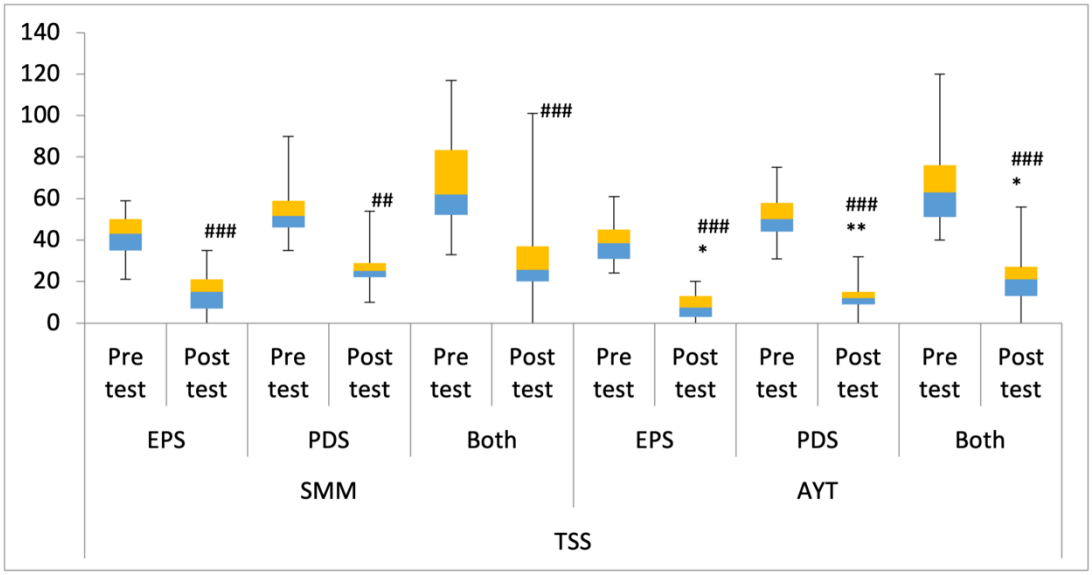


Figure 1: Reduction in total symptom score in all three subgroups of FD

- **<u>AYT is significant over SMM in EPS and overlap groups at p<0.05 and PDS group at p<0.01.</u>**

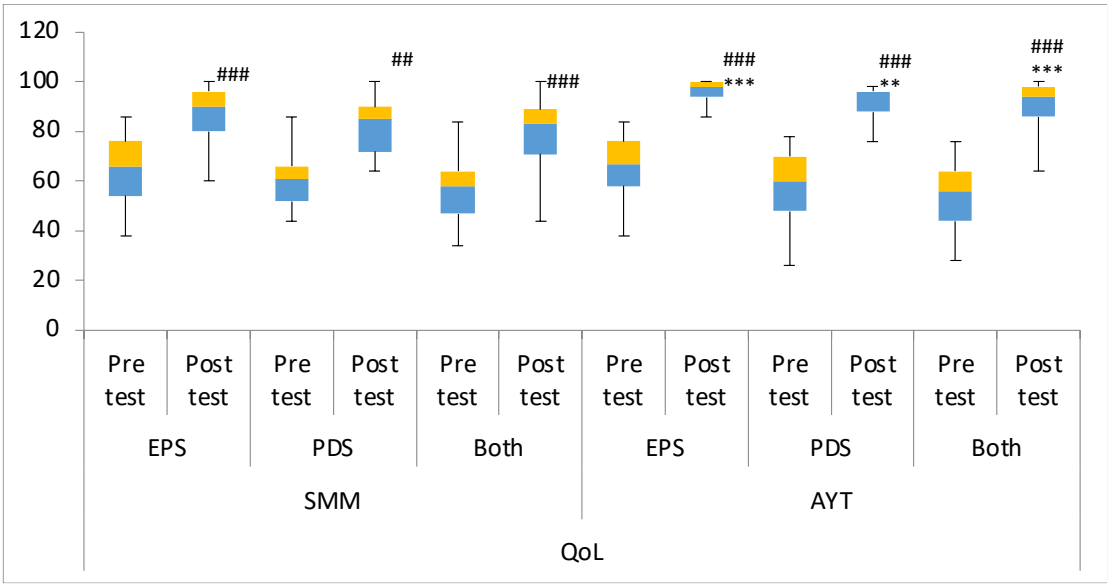


Figure 2: Improvement in QoL scores in all three subgroups of FD

- **AYT is significant over SMM group in EPS, overlap subgroups at p<0.001 and PDS subgroup at p<0.01.**

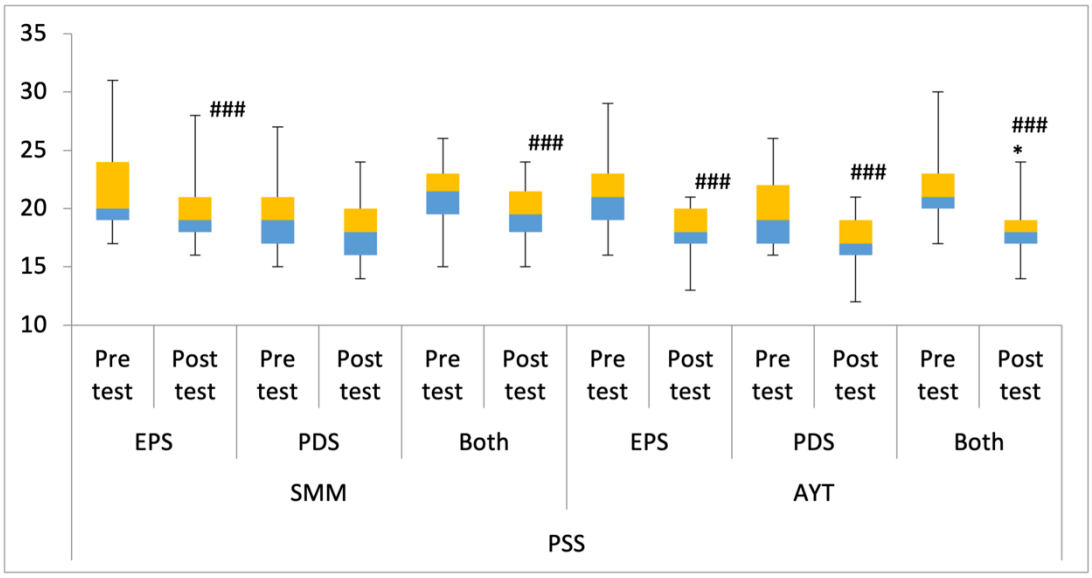


Figure 3: Reduction in PSS score in all three subgroups of FD

- **AYT is significant over SMM in reducung PSS score in overlap group (p<0.05), however, it is not significant over SMM in EPS and PDS subgroup.**

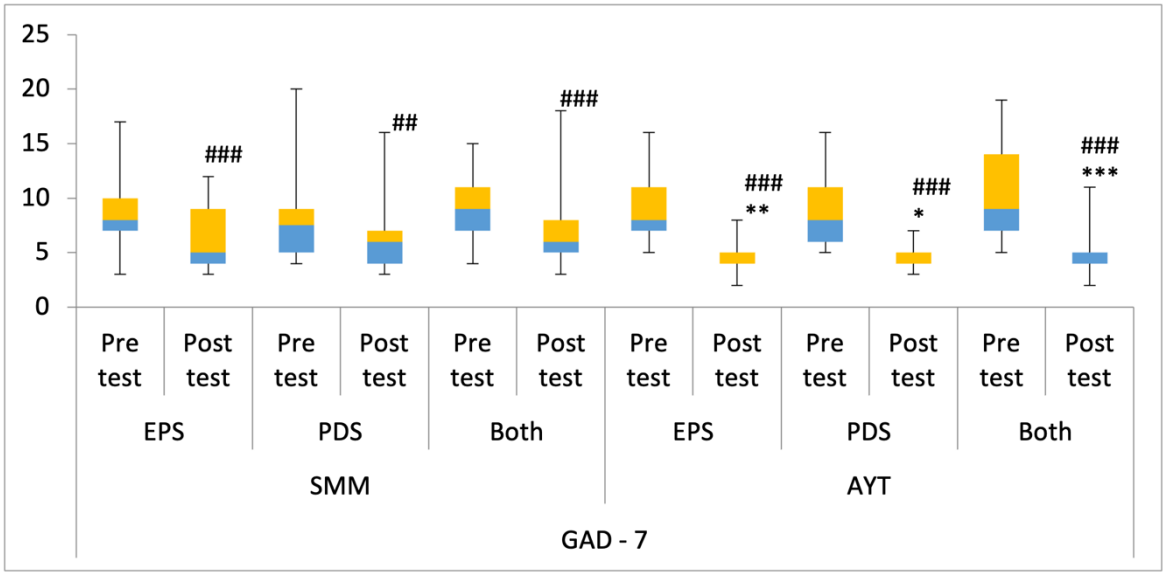


Figure 4: Reduction in anxiety scores in all three subgroups of FD

- **<u>AYT is significant over SMM in reducing anxiety scores in EPS (p<0.01), PDS (p<0.05) and overlap subgroup (p<0.001).</u>**

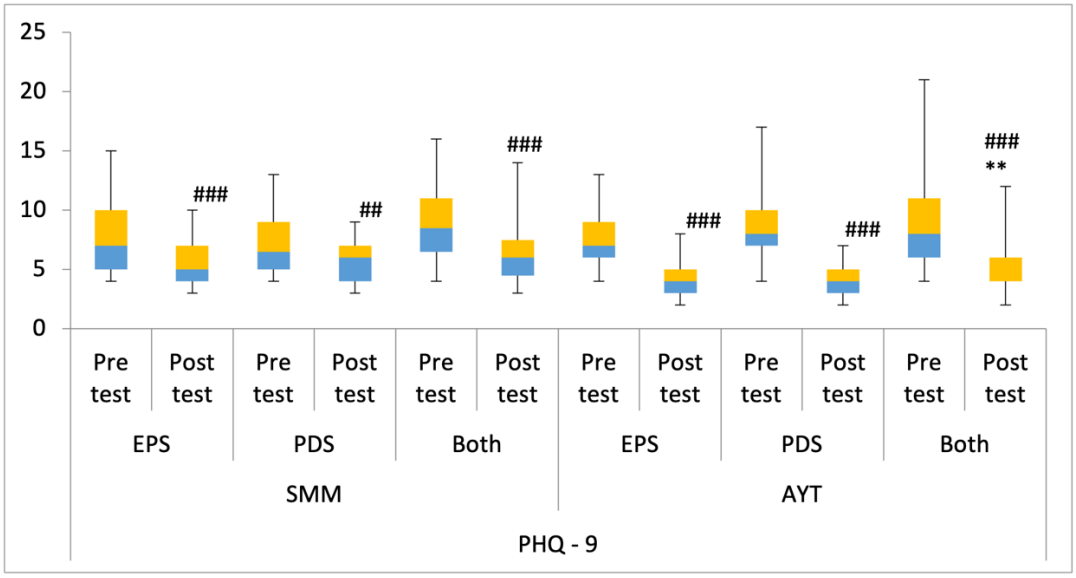


Figure 5: Reduction in depression scores in all three subgroups of FD

- **<u>AYT is significant over SMM in reducing depression scores in overlap subgroup (p<0.05) but not in EPS & PDS groups.</u>**

When patients are sub grouped under EPS, PDS and overlap categories, AYT is significant over SMM in reducing TSS, improving QoL and reducing anxiety in all

subgroups. However, AYT is not significant for reducing PSS and depression when compared to SMM in EPS and PDS subgroups but significant in overlap groups.

6.7 Effect of two subgroups of AYT, viz., AYT with Laghoo Shankh Prakshalana (LSP) & AYT without LSP on TSS, QoL, PSS, GAD-7 & PHQ-9

In our study AYT group was further subdivided into two groups – AYT – LSP subgroup in which the cleansing practise LSP was given (in those subjects who were able to come for in person sessions) and AYT- no LSP group in which LSP could not be given. Hence, a sub-group analysis was done with the two yoga groups, viz. AYT-LSP, AYT- no LSP and SMM group. Table 6 represents the intra-group as well inter-group comparison for all three subgroups for change in TSS.

Table 6: Effect of three subgroups on TSS

		AYT - LSP	AYT – No LSP	SMM	KW-ANOVA
TSS	Pre	50(41,61)	58(44.5,71)	52(44,64)	0.351
	Post	9(5.5,15)	20 (15.25,25.75) [a3]	22(15,31) [a3]	< .001
	Wilcoxon	<0.001	<0.001	<0.001	

Where 'a' signifies significantly different from EPS, 'b' signifies significantly different from PDS. 1 refers to significant at <0.05, 2 refers to significant at <0.01, 3 refers to significant at <0.001 (Using post hoc Dunn's test)

- There is improvement in TSS in all three subgroups ($p<0.001$), however the KW-ANOVA test reveals significant difference among the three subgroups ($p<0.001$).
- The post hoc Dunn's test further reveals AYT-LSP subgroup significant over AYT - no LSP and SMM subgroup in improving TSS ($p<0.001$).
- There is no significant difference between AYT - no LSP and SMM group in improving TSS.

Table 7 represents within group changes as well as between the group comparison of QoL in all three subgroups.

Table 7: Effect of three subgroups on QoL

		AYT - LSP	**AYT – No LSP**	**SMM**	**KW-ANOVA**
QoL	Pre	60(47,71)	61(50.5,69.5)	60(50,68)	0.989
	Post	98(91.5,100)	92(88,96)[a1]	86(74,92)[a3b1]	< 0.001
	Wilcoxon	<0.001	<0.001	<0.001	

Where 'a' signifies significantly different from EPS, 'b' signifies significantly different from PDS. 1 refers to significant at <0.05, 2 refers to significant at <0.01, 3 refers to significant at <0.001 (Using post hoc Dunn's test)

- Post hoc Dunn's test further reveals AYT-LSP and AYT-no LSP subgroup to be significant over SMM subgroup in improving QoL at $p<0.001$ and $p<0.05$ respectively.
- Improvement in QoL in AYT-LSP subgroup is significant over AYT-no LSP subgroup ($p<0.05$).

Table 8 represents within group changes as well as between the group comparison of reduction in stress scores in all three subgroups.

Table 8: Effect of three subgroups on PSS

		AYT - LSP	**AYT – No LSP**	**SMM**	**KW-ANOVA**
PSS	Pre	21(19,23)	21(20,23)	21(19,23)	0.799
	Post	18(16,19)	19(18,20)[a1]	19(18,21)[a3]	< .001
	Wilcoxon	<0.001	<0.001	<0.001	

Where 'a' signifies significantly different from EPS, 'b' signifies significantly different from PDS. 1 refers to significant at <0.05, 2 refers to significant at <0.01, 3 refers to significant at <0.001 (Using post hoc Dunn's test)

- Post hoc Dunn's test reveals AYT-LSP group is significant over AYT - no LSP ($p<0.05$) and SMM group ($p<0.001$) in reducing PSS scores.

Table 9 represents within group changes as well as between the group comparison of reduction in anxiety scores in all three subgroups.

Table 9: Effect of three subgroups on GAD-7

		AYT - LSP	**AYT – No LSP**	**SMM**	**KW-ANOVA**
GAD-7	Pre	9(7,12)	8(6.25,11)	8(6,11)	0.209
	Post	4(4,5)	4(4,5)	6(5,8)[a3b3]	< .001
	Wilcoxon	<0.001	<0.001	<0.001	

Where 'a' signifies significantly different from EPS, 'b' signifies significantly different from PDS. 1 refers to significant at <0.05, 2 refers to significant at <0.01, 3 refers to significant at <0.001 (Using post hoc Dunn's test)

- Post hoc Dunn's test reveals both AYT-LSP and AYT- no LSP subgroup to be more significant over SMM group ($p<0.001$) in reducing anxiety scores**.**

Table 10 represents within group as well as between the group comparison of reduction in depression scores in all three subgroups.

Table 10: Effect of three subgroups on PHQ - 9

		AYT - LSP	**AYT – No LSP**	**SMM**	**KW-ANOVA**
PHQ-9	Pre	8(6,10)	8(6.25,10)	8(5,10)	0.536
	Post	4(3,5)	5(4,7)[a1]	5(4,7)[a3]	< .001
	Wilcoxon	<0.001	<0.001	<0.001	

Where 'a' signifies significantly different from EPS, 'b' signifies significantly different from PDS. 1 refers to significant at <0.05, 2 refers to significant at <0.01, 3 refers to significant at <0.001 (Using post hoc Dunn's test)

- Post hoc Dunn's test reveals AYT-LSP group to be significant over AYT-no LSP ($p<0.05$) and SMM group ($p<0.001$) in reducing depression scores**.**

When intervention in sub grouped as AYT-LSP, AYT-no LSP and SMM groups, AYT-LSP is more significant than other two groups in improving TSS, PSS and depression. However, both AYT groups are significant than SMM in improving QoL and anxiety.

6.8 Effect of H. Pylori status on treatment response

Subjects on the basis of H. pylori status were further divided into H. pylori positive, H. pylori negative and unknown status (in which H. pylori testing was not done) subgroups. Any difference in treatment response in the subgroups was analysed using KW-ANOVA with the Δ % values. It was observed that there was **no difference in the treatment response in the three subgroups based on H. pylori status**.

All the three subgroups responded equally to the treatment given irrespective of the H. pylori status. We conclude that H. pylori status does not significantly affect the treatment response.

7 Summary & Conclusion

Adjuvant yoga therapy is a novel addition in the management of FD. In our study, use of yoga therapy as an adjuvant to SMM has shown an added benefit in FD patients in all outcome parameters including total symptom score, QoL, stress, anxiety and depression.

While 68.9% patients in SMM group reported sufficient symptom relief, **93.6% patients in AYT group reported sufficient relief in symptoms** (≥50%). AYT group has 6.6 times more chances of high recovery (≥50% relief) than SMM group in our study (Odds Ratio - 6.611 with Confidence Interval 2.369 – 18.452). **AYT-LSP group in our study showed greater effect** than both AYT-no LSP group and SMM group. H. pylori status didn't affect the treatment response to medications or Yoga therapy.

In conclusion, the findings provide initial evidence for using Yoga therapy as an adjuvant treatment to SMM for providing symptomatic relief in relatively more patients as well as enhance their QoL, reduce stress, anxiety and depression that may be causative factors in developing symptoms. This study should also pave the way for more future research in this area with varied interventions and adding more outcome parameters like inflammatory markers or evaluating gut microbiota.

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Appendix

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Case Report

Adjuvant yoga therapy for symptom management of functional dyspepsia: A case series

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ABSTRACT

Functional Dyspepsia (FD), commonly called chronic indigestion, comes under the umbrella of 'Disorders of Gut–Brain Axis'. It manifests as a cluster of upper gastrointestinal symptoms including epigastric pain or burning, postprandial fullness and early satiety. Since the pathophysiology is complex, it is often difficult to effectively manage and significantly impacts the patient's quality of life. This case series aims to elucidate the role of Yoga as an adjuvant therapy to modern medicine in providing relief of dyspeptic symptoms in such patients. Yoga is an ancient Indian mind-body practise that has the potential to be used for various brain-gut disorders. Apart from treating the gut disorders from top down (mind-gut) pathway, it may have more direct physiological effects as well. Researches on IBS and one research on abdominal pain related FGID have shown Yoga therapy to be effective in ameliorating the symptoms.

In this study, we present three such cases (1 male and 2 female) having a clinical diagnosis of FD in detail. These patients were initially non-responsive to medications but later showed remarkable improvement in symptoms within one month of added Yoga therapy intervention. This study was conducted as a part of a larger study conducted at a tertiary hospital in Pondicherry in collaboration between its Yoga department and Medical Gastroenterology Department. Yoga therapy protocol was given along with their regular medical management for a month. Gastrointestinal Symptom Rating Scale (GSRS) and Dyspepsia Symptom Score questionnaires were used to assess symptoms before and after the intervention period. All three patients showed marked reductions in symptom scores both in the GSRS and Dyspepsia Questionnaire. The present case series suggests effect of adjuvant Yoga therapy in reducing symptoms of functional dyspepsia. Future studies may clarify the psycho-physiological basis of the same.

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1. Introduction

Functional Dyspepsia (FD), commonly known as, chronic indigestion is an upper gastrointestinal disorder that consists of a cluster of symptoms including epigastric pain or burning, postprandial fullness and early satiety without any organic or structural cause. Associated complaints may include bloating, belching, nausea, vomiting etc. Rome- IV further categorizes FD into broadly two categories: (i) Epigastric Pain Syndrome (EPS) which includes the presence of bothersome epigastric pain or/and burning, at least once a week for 3 months with symptom onset at least 6 months prior. (ii) Postprandial Distress Syndrome (PDS) which includes bothersome fullness after meals or/and early satiety present at least 2–3 days a week for 3 months with symptom onset at least 6 months prior [1,2].

Estimated prevalence of FD in the Rome Foundation global survey, as per Rome IV criteria in the general population stands at 7.2% [3]. In India prevalence of uninvestigated dyspepsia (UD) is estimated between 7.5% and 49% differing across various states [4].

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[JGLD] Editor Decision

Prof. Dr Dan L Dumitrascu <editor@jgld.ro> Wed, Jun 14, 2023 at 3:35 PM
To: Garima Setia <setia.garima@gmail.com>, Ananda Balayogi Bhavanani <yognat@gmail.com>, Meena Ramanathan <saineema@gmail.com>, Nilakantan Nilakantan Nilakantan <n.ananthk@gmail.com>, Vinod Boopathy <drbvinoth@gmail.com>, "B. Sajeeth Manikanda Prabu" <drsmp.sajeeth@gmail.com>, Balanehru Subramanian <balanehrusbv@gmail.com>

Dear Professor/Dr. Garima Setia, Ananda Balayogi Bhavanani, Meena Ramanathan, Nilakantan Nilakantan Nilakantan, Vinod Boopathy, B. Sajeeth Manikanda Prabu, Balanehru Subramanian,

We have reached a decision regarding your submission to Journal of Gastrointestinal and Liver Diseases, "Yoga therapy in functional dyspepsia – A narrative review".

Our decision is to: Accept Submission

Best regards,

Prof. Dan L. Dumitrascu, MD, PhD, AGAF
Editor-in-chief
Journal of Gastrointestinal and Liver Diseases

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